

J K Laser Aesthetics Inc.

Pelleve /PelleFirm[®]™ RF Skin Treatment System Consent Form

Patient Name: _____

Date: _____

As a patient, it is important that you understand the possible results and risks of **radiofrequency (RF) skin treatment with Pelleve[®] or PelleFirm[™] handpieces (Pelleve)**. Please read this document carefully. Before signing this document, ask about any aspect of this document or the procedure that you do not understand.

Pelleve System equipment may present a hazard to patients with active implanted devices (e.g. pacemakers, defibrillator, cochlear implant, diabetic pump, etc.) or inactive metal implants (e.g. artificial jaw/joint, metal IUDs, etc.) that are near the treatment area. Tell your clinician if you have any metal or active implants.

Since ongoing patient feedback is required during treatment, if you have any nerve insensitivity to heat in the treatment area, you should not be treated with Pelleve.

Tell your clinician if you have a history or current symptoms of any of the following conditions:

- Skin disease in the treatment area
- Active cut, wound, or infection in the treatment area, including cold sores
- Collagen or vascular disease (e.g. scleroderma)
- Autoimmune disease (e.g. lupus or severe dermatitis)
- Any disease that inhibits pain sensation

Tell your clinician if you have a history of or are currently taking any of the following:

- Oral steroids
- Topical steroids in the treatment area
- Isotretinoin (Accutane[®]) or tretinoin (Retin-A[®]),
- Glycolic or Salicylic Acid
- Any medication that can cause dermal hypersensitivity or affect skin characteristics

Inform the clinician if you have recently received other types of treatment such as neurotoxins, fillers in the treatment area.

Pelleve equipment is unstudied and unknown for pregnant or lactating patients, patients with autoimmune disease, diabetes, or herpes simplex. All patients are different and exact results of the treatment(s) cannot be predicted or guaranteed.

During Treatment

All jewelry and makeup, including lotions, eyeliner and eye shadow should be removed from the treatment area prior to the procedure.

Cut, wounded or infected skin should not be treated as this could promote infection and injury.

Ensure you are well hydrated prior to treatment. With good hydration, tissue is more responsive to

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heat.

Excessive hair in the treatment area will need to be removed (shaved or closely trimmed) prior to treatment as heating may be compromised. Thick facial hair should be clean shaven.

During the treatment you should feel warmth and heat and provide ongoing feedback to the clinician performing the treatment. Therefore no anesthetic (local, oral, or systemic) should be used prior to or during the treatment. Additionally, if you have nerve insensitivity to heat anywhere in the treatment area, you should not be treated. Inadequate or impaired feedback may lead to burns or injury. Ongoing feedback should be provided by you to the individual performing the treatment to ensure a safe and effective treatment.

Slight discomfort may be experienced while undergoing treatment due to the strong heating sensation generated. Typically the discomfort is mild and temporary during the procedure and localized within the treatment area. Inform the clinician immediately if you experience any pain or a burning sensation.

After Treatment

Studies indicate the possible side effects are usually treatment- site related and include mild discomfort during the procedure localized within the treatment area. Mild swelling and redness may occur which typically goes away within 2 to 24 hours. There is the possibility that additional risk factors of radiofrequency skin treatments exist that are not yet known.

Possible Risks

Risks associated with Pelleve are well known and include:

- Mild swelling post-treatment
- Mild redness post-treatment

Swelling and redness are temporary in nature and typically resolve quickly. As with any radiofrequency treatment, burning is also possible. In order to avoid a burn, it is important that you tell your clinician if the treatment becomes too hot.

My signature below confirms my understanding that the Pelleve and/or PelleFirm treatment is a cosmetic procedure and is not covered by insurance. It has been explained to me that three or more treatments are recommended to achieve the best results. I understand that there are other treatment options such as microdermabrasion, chemical peels, filler injections, or no treatment at all. There is no guarantee of results and no refund of payments for the procedure will be made.

My signature below signifies that all my questions have been answered by the clinician providing the treatment. I understand the risks, complications, expected results, and expense of treatment. I have read and understand this document and give my consent for treatment.

Patient Name: _____ Signature: _____ Date: _____